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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,293	12/07/2004	Anders Larsson	PU0246	4704
22840 7590 06/22/2007 GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855			EXAMINER	
			ZEMEL, IRINA SOPJIA	
			ART UNIT	PAPER NUMBER
			1711	
•				
			MAIL DATE	DELIVERY MODE
			06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Application No.	Applicant(s)				
		10/517,293	LARSSON ET AL.				
		Examiner	Art Unit				
		Irina S. Zemel	1711				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
WHIC - Exter after - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in the may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1)⊠	Responsive to communication(s) filed on <u>27 April 2007</u> .						
′=	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims						
4) 🖂	4)⊠ Claim(s) <u>1-16 and 18-29</u> is/are pending in the application.						
	4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.						
· · · · · · · · · · · · · · · · · · ·	5) Claim(s) is/are allowed.						
	Claim(s) <u>1-16 and 29</u> is/are rejected.						
• ==	Claim(s) is/are objected to.						
8)[_]	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	ion Papers						
9)	The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority ι	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
7 8	See the attached detailed Office action for a list	of the certified copies not receive	d.				
Attachmen	• •						
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da					
3) 🛛 Infor	mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date 12-7-2004.	5) Notice of Informal P 6) Other:					

## **DETAILED ACTION**

## Election/Restrictions

Applicant's election without traverse of Invention Group I in the reply filed on 4-27-2007 is acknowledged.

Claims 18-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for branched hydrophilic polyhydroxy-functionl polymers (with the required DB) that are derived from sugar or sugar alcohols crosslinked with epichlorohydrin (as per combined claims 7 and 9), does not reasonably provide enablement for any polyhydroxyfunctional polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1989) otherwise undue experimentation would be involved in determining how to practice and use applicant's invention. Although the statute itself does not use the phrase "undue experimentation", it has been interpreted to require that the claimed

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invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation as stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Specifically, in *In re Wands* the Court set forth a non-exhaustive list of factors to be considered in determing whether undue experimentation would be involved in making and/or using the claimed invention. These factors include, but are not limited to:

(a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applying these factors to the claims of the instant application, it is noted that the specification provides no direction or working examples (cf. factors (f) and (g)) for any polymer other than epichlorohydrin crosslinked sugar. Thus, the only portions of the specification that describe the polymer recited in claims 1-16 and 29 is the second full paragraph on page 12 and illustrative examples and these paragraphs exemplify only epochlorohydrin crosslinked polysaccharides only not any other polymer. There is no guidance as to how obtain any other polymers with specified DB that can be attaches to the polymeric matrix at multiple points.

Furthermore, in view of the breadth of claim 1 (cf. factor (a)) which encompasses innumerable polyhydroxy functional polymers it is urged that the quantity of

experimentation (cf. factor (h)) involved in order to reach a usable embodiment would be great. In light of the above factors, it is concluded that undue experimentation would be involved to make and use the invention as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim 1 recites "each polymer has been tethered...", however, the same claim recites branched hydrophilic polyhydroxy functional polymers that include hyperbranched polymers. It is not clear which of those polymers are "tethered to the base matrix". It creates confusion how "each polymer" which is not branched is attached to the matrix at multiple points, and also what exactly is meant by "each polymer", which appears to refer to each polymer chain of the branched polymer.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 3897414 discloses compositions containing dextrai and Ficoll, and 330747 discloses branched polyhydroxyfunctional polymers identical to the polymers attached to the matrix as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Irina S. Zemel Primary Examiner Art Unit 1711

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